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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,349	04/08/2004	John J. Merianos	FDN-2837	8164

7590 03/01/2007  
Attn: William J. Davis, Esq.  
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Building No. 10  
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EXAMINER
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WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/820,349

Applicant(s)

MERIANOS ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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Claims 1-10 are presented for examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to an antimicrobial composition, which is active against bacteria, yeast, and mold spores, consisting essentially of, by wt.

- (a) 40-60% of a 1,2-diol and selected from the group consisting of 1,2-pentanediol, 1,2-hexanediol and 1,2-octanediol;
- (b) 40-60% of a phenoxyethanol; and
- (c) 0-10% of a co-biocide selected from the group consisting of sorbic acid, benzoic acid, dibromodicyanobutane, iodopropynl butyl carbamate and 1,2-benzisothiazoline-3-one.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the instant antimicrobial composition is effective against all gram-negative bacteria, gram-positive bacteria, all types of yeast, and all types of mold spores

The breadth of the claims

The claims are very broad and inclusive to all types of bacteria (gram-negative and gram-positive), all types of yeast, and all types of mold spores.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples showing the instant antimicrobial composition is effective against all gram-negative bacteria such as Salmonella, Helicobacter and Stenotrophomonas; all gram-positive bacteria such as Streptococcus, Enterococcus and Bacillus anthracis (Anthrax); all types of yeast such as Saccharomyces cerevisiae; and all types of mold spores such as Stachybotrys chartarum (sick-building syndrome).

The working examples disclosed in applicants' specification showing the instant antimicrobial composition is effective against gram negative bacteria (E. coli and P. aeruginosa); gram-positive (Staph. aureus); yeast (C. albicans); mold (A. niger); and B. cepacia only.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the other types of gram-negative bacteria, gram-positive bacteria, all types of yeast and all types of mold spores were eradicated by the instant antimicrobial composition. The level of experimentation needed to determine the instant antimicrobial composition would be able to treat bacterial infections caused by bacteria (all types of gram-negative and all types of gram-positive), all types of yeast, and all types of mold spores of claim 1 is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-10 are not allowed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rendered indefinite because the Examiner cannot determine if “(a) is 43.3; (b) is 55.3” is the weight in grams, milligrams or percentage (%). Clarification is required.

Claim 7 is not allowed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1238651 A1, hereby known as Morrelli et al. in view of Windholz et al., THE MERCK INDEX, 10<sup>th</sup> Edition, pps. 1247-1248, abstract no. 8567 (1983).

Morrelli et al. teach a composition comprising caprylyl glycol in combination with 1,2-octanediol with IPBC (iodopropynyl butyl carbamate) and phenoxyethanol (see page 6, paragraph [0057]). The same paragraph teaches the instant composition provides anti-microbial protections bacteria and fungi. Note the bacteria are *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus*, *Candida albicans*, and *Aspergillus niger*. Note particular to page 6, paragraphs [0058] and [0060] teaches the instant composition can be used in sunscreen formulations and other appropriate formulations for topical dermatological or pharmaceutical applications (same as personal care products of claims 8-10).

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred weight of each agent in the

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instant antimicrobial as set forth in claims 1, 3, 5 and 7. However, to determine a weight of each individual agent in the instant antimicrobial composition having the optimum effectiveness together is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum weight of each agent to get the maximum effectiveness in the absence of evidence to the contrary.

The instant invention differs from the cited reference in that the cited reference does not teach addition of sorbic acid or the sorbic acid can use in the instant antimicrobial composition. However, the secondary reference, Windholz et al., teaches sorbic acid as a well-known mold and yeast inhibitor.

Clearly, one skilled in the art would have assumed that the addition and/or the use of sorbic acid in the instant antimicrobial composition is obvious since the combination of each individual agent (well-known to be effective against bacteria, fungi and mold) into a single composition would give an additive effect in the absence of evidence to the contrary.

Claims 1-10 are not allowed.


The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:00 am-8:00 pm.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
February 26, 2007